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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,715	07/20/2001	Brian J. Cox	18455.11	1492

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/909,715

Applicant(s)

COX, BRIAN J.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44-47, 54-56, 59-61 and 64-100 is/are pending in the application.
- 4a) Of the above claim(s) 59, 70-75, 78-80 and 86 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 81-85 and 95-100 is/are allowed.
- 6) ☒ Claim(s) 44-47, 54-56, 60, 61, 64-69, 76, 77 and 87-94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Objections*

1. Claims 99 and 100 are objected to because of the following informalities:

The preamble for the claims recite an apparatus. However, the claims are dependent of method claim 96. Therefore, appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 44-47, 54-56, 60, 61, 64, 67-69, 76, 77 and 87-91 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,234,456 to Silvestrini.**

(claim 44) Silvestrini discloses an implant comprising an expandable stent **10** having fenestrations, said expandable stent comprising a substantially cylindrical body member located between two ends and defining a lumen therein; wherein the stent is expandable between a first diameter or undeployed configuration to a second diameter or deployed configuration (col. 2, lines 48-58); and a reactive or hydrophilic material on a portion of said stent, wherein the hydrophilic material has first state of protonation prior to implantation and undergoing a change to a second state of protonation after implantation when the hydrophilic material comes in contact with tissue fluids, said change in state resulting in the expansion of the reactive material. Therefore, the

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fenestration (or openings) will inherently decrease in size when the stent wall expands or swells.

(claims 45 and 46) Silvestrini discloses the hydrophilic material being a hydrogel (col. 2, line 47).

(claims 47 and 56) The hydrophilic material is reactive to tissue fluids, which has a ph value of around 7.4.

(claim 54) The hydrophilic material is integrally formed within the interior wall of the stent.

(claim 55) The hydrophilic material would inherently be larger after swelling.

(claims 60 and 61) The stent is delivered by a catheter (col. 2, lines 48-51), which is a mechanical means.

(claim 64) The stent is formed from polyurethane and polyvinyl alcohol (col. 2, line 37 and 47).

(claim 67) The second diameter or deployed configuration is capable of being equal to a diameter of a blood vessel.

(claim 68) Silvestrini discloses that the stent absorbs tissue fluids and swells to inflate said stent. It would therefore be inherent that the stent will expand radially and axially as the stent swells.

(claim 69) Fig. 3 of Silvestrini also discloses an expandable, woven stent having fenestrations, said stent having a cylindrical body member located between two ends and having a lumen therein, wherein the stent is expandable between a first diameter or undeployed configuration to a second diameter or deployed configuration (col. 2,

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lines 48-58); and a reactive or hydrophilic material within hollow fibers **26** interwoven with a solid woven fiber **28**, wherein the hydrophilic material absorbs tissue fluids to increase the size of the stent, which would inherently decrease the size of fenestrations.

(claims 76 and 88) See the rejection to claim 69. The stent is viewed as helical.

(claims 77 and 87) See the rejection to claim 44. The stent is viewed as reticulated.

(claim 89) see the rejection to claim 44 and the following: the reactive material is a stimulus expandable hydrogel (col. 2, line 47).

(claims 90 and 91) see the rejection to claims 47 and 56.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**6. Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini and in view of US 5,843,089 to Sahatjian et al.**

Silvestrini teaches all the limitations of the claim, except for the stent comprising radio-opaque or echo-genic materials. However, Silvestrini does disclose an embodiment wherein the stent is formed from hollow fibers and solid fibers (Fig. 3). Silvestrini provides the material used for the hollow fibers but is silent with regards to the material for the solid fibers. Sahatjian discloses a similar woven stent, as shown in Figs. 1-3, and wherein the stent is formed of solid fibers comprising stainless steel (col. 1, line 36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made modify the device of Silvestrini to use stainless steel solid fibers because stainless steel is corrosion resistant and is also radio-opaque, which would make it easier for the practitioner to deliver the stent to the target area.

**7. Claims 92-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini and in view of US 6,060,534 to Ronan et al.**

Silvestrini discloses the claimed invention except that the hydrogel is a polyvinyl alcohol instead of an ethylenically unsaturated monomer with an ionizable functional group comprising either an amine or carboxylic acid. However, Ronan discloses a hydrogel comprising an ethylenically unsaturated monomer with an ionizable amine or carboxylic acid (col. 2, lines 52-67). Ronan shows that a hydrogel that is an equivalent structure known in the art. Therefore, because these two hydrogels were art-recognized equivalents at the time the invention was made, one of ordinary skill in the

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art would have found it obvious to substitute the hydrogel of Ronan for the hydrogel of Silvestrini.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. **Claims 44-47 and 69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 17, 20 and 22 of copending Application No. 10/763,975.** Although the conflicting claims are not identical, they are not patentably distinct from each other because elements of the claims in the instant application are to be found in the claims of the copending application.

As to claim 44 of the instant application, claims 1, 5 and 17 of the copending application discloses all the elements in the claim, such as an expandable structure (or

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stent) and a reactive material. The difference between the claims merely lies on the terminology used to recite the elements. However, they are still obvious variants of the same subject matter and would therefore be obvious to one of ordinary skill in the art.

As to claims 45-47 of the instant application, see claims 2-4 of the copending application, respectively.

As to claim 69 of the instant application, see claims 7 or 22 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Allowable Subject Matter***

10. The indicated allowability of claim 69 is withdrawn in view of the newly discovered reference(s) to Silvestrini. Rejections based on the newly cited reference(s) is provided above.

11. Claims 81-85 and 95-98 are allowed.

12. Claims 99 and 100 would be allowable if rewritten to overcome the claim objections recited above.

13. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to teach a method of treating a vascular aneurysm comprising, inter alia, the steps of providing an expandable support device having a cylindrical body member with fenestrations; and activating a reactive material disposed on said expandable support device to increase the resistance of blood flow through the fenestrations due to expansion of the hydrogel. The device of Silvestrini is not taught



for treating vascular aneurysms and is silent with regards to increasing the resistance of blood flow through the stent's fenestrations.

### ***Response to Arguments***

14. Applicant's arguments with respect to claims 44-56, 60, 61, 64-69, 76, 77 and 87-94 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

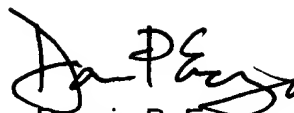
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read 'Darwin P. Erez', is written over the printed name.

Darwin P. Erez

Examiner

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